NOV 18 2011 K 111960

SECTION 5 - 510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: _____

Submitter ELITech Vital Scientific BV
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Contact Colinda van den Broek (Email: c.vandenbroek@elitechgroup.com)

Date of Preparation June 24, 2011

Device names

Trade/proprietary Name: **ELITech Clinical Systems ISE TotalCO_2 Electrode**
Common or Usual Name: Total CO_2 ISE
Regulatory:

Code	*Name*	*Class*	*Regulation*	*Regulation Name*	*Panel*
KHS	enzymatic, Carbon - Dioxide	II	21 CFR 862.1160	Bicarbonate/Carbon dioxide test	75 Clinical Chemistry

Trade/proprietary Name: **ELITech Clinical Systems ISE Calibrators**
Common or Usual Name: ISE Calibrator
Regulatory:

Code	*Name*	*Class*	*Regulation*	*Regulation Name*	*Panel*
JIX	calibrator, multi-analyte mixture	II	21 CFR 862.1150	Calibrator	75 Clinical Chemistry

Establishment Information:

The establishment registration number for ELITech Vital Scientific BV is 8030478.
The establishment registration number for ELITech SEPPIM SAS is 3007662974.
The establishment registration number for ELITech Wescor USA is 1717966.
The owner operator number for ELITech North America (Wescor, Logan, UT, USA) is 1717966.

Predicate device:

Predicate Instrument or reagent	*510(k) Number*	*Product code(s)*
• ROCHE Diagnostics, COBAS Integra Bicarbonate liquid (CO2-L) • Roche Diagnostics, Ammonia/Ethanol/CO2 calibrator	K031879	KHS

Substantial Equivalence:	The ELITech Clinical Systems ISE Total CO2 Electrode calibrated with ELITech Clinical Systems ISE Calibrators is demonstrated to be substantially equivalent to the Roche Diagnostics COBAS Integra Bicarbonate liquid calibrated with Roche Diagnostics Ammonia/Ethanol/CO2 Calibrator
Device description	The ELITech Clinical Systems ISE Total CO2 Electrode system is comprised of the electrodes plus ISE Reference Solution, ISE Diluent, ISE Calibrators.
Performance Standards	To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Intended Use
See Indications for Use following

Indications for Use:

ISE Total CO_2 Electrode
The Total CO_2 electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of carbon dioxide in serum and plasma. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Comparison to Predicate device

Similarities and Differences		
ISE MODULE	ELITech Clinical Systems Device (Selectra ProM ISE Module)	Predicate device (Selectra ProM ISE Module K102647)
Intended use/Indications for Use	The Selectra ProM ISE module is an electrometer used for measurement of electrolytes.	Same
Intended use	used for the quantitative *in vitro* diagnostic determination of sodium (Na^+), potassium (K^+), chloride (Cl^-) and total CO_2 in human serum and plasma	used for the quantitative *in vitro* diagnostic determination of sodium (Na^+), potassium (K^+), and chloride (Cl^-) in diluted serum, plasma and urine
Indication for Use	Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.	Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Test principle		
Assay protocol	Indirect potentiometry measurement with Ion-Selective Electrode	Same
Sample type	Serum or lithium heparinized plasma free of hemolysis, obtained anaerobically for total CO_2.	Serum and hemolysis-free plasma.
General information		
Expected values	Sodium: Serum/plasma : 136-145 mmol/L	Same

	Potassium: Serum: 3.5 -5.1 mmol/L Plasma: 3.4 – 4.5 mmol/L Chloride: Serum/Plasma: 98 – 107 mmol/L	Same Same
Method comparison	Sodium on serum Same Potassium on serum Same Chloride on serum Same	Sodium on serum Same Potassium on serum Same Chloride on serum Same
General information	ELITech Clinical Systems Device (Selectra ProM ISE Module)	Predicate device (ROCHE Diagnostics CO2-L, Bicarbonate liquid with Roche Diagnostics Ammonia/Ethanol/CO2 Calibrator , K031879)
Expected values	23-29 mEq/L	22-29 mol/L
Reagent composition/technology	**ISE reference including CO2** *Composition*: Buffered solution with surfactant containing : 1.75 of CO_2 mmoL/L *Storage:* Store at 10-30 °C. This solution is stable until the expiry date stated on the label. Do not freeze.	**Reagent R1** : *Composition:* Phosphoenolpyruvate ≥ 40 mmol/L NADH analog ≥ 2.0 mmol/L MDH (porcine) ≥ 314.3 µkat/L PEPC (microbial) ≥ 30.8 µKat/L Liquid form, ready to use *Storage:* Store at 2-8 °C. This solution is stable until the expiry date stated on the label.
Performance characteristics		
Electrode slope range	Total CO_2: - 40 to -10 mV	Not applicable
Measuring range	Total CO_2: 10.8 – 43.0 mEq/L	0.5-50 mmol/L
Precision	Total CO_2 : **Within run** Level 12.1 mEq/L CV=3.9% Level 19.9 mEq/L CV=2.3% Level 27.5 mEq/L CV=2.3% **Total**	**Within run** Level 18.7mmol/L CV=0.72% Level 31.6 mmol/L CV=0.84% Level 9.09 mmol/L CV=1.34% Level 24.9 mmol/L CV=0.67% **Total**

	Level 12.1 mEq/L CV=6.8% Level 19.9 mEq/L CV=5.4% Level 27.5 mEq/L CV=5.2%	Level 18.2mmol/L CV=1.41% Level 31.2 mmol/L CV=0.81% Level 8.30 mmol/L CV=2.23% Level 23.7 mmol/L CV=1.04%
Method Comparison	Total CO_2 y=0.908 x + 2.2 mEq/L r= 0.985 range: 9.7 to 44.9 mEq/L	 y=1.019x – 0.19 mmol/L r= 0.9995 range: 2.46 to 46 mmol/L
Calibration Frequency	It is recommended to recalibrate after setting-up of a new vial of ISE Reference Solution or of ISE Diluent then every 4 hours when quality control results fall outside the established range, after replacing electrode, and after ISE cleaning and maintenance.	Each lot and as required following quality control procedures.
Controls	Recommended quality control material (not included): ELITech Clinical Systems ISE CONTROL I (Level 1) ELITech Clinical Systems ISE CONTROL II (level 2)	Recommended quality control material: Roche Diagnostics Precinorm U Roche Diagnostics Precipath U
Limitations	Total CO_2: **Unconjugated bilirubin:** No significant interference up to 30 mg/dL (513 µmol/L). **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 µmol/L). **Hemoglobin** : No significant interference up to 300 mg/dL. **Turbidity:** No significant interference up to 614 mg/dL (7 mmol/L). **Acetylsalicylate:** No significant interference up to 40 mg/dL (2.2 mmol/L). Concentrations above the therapeutic levels will interfere and cause erroneous results. **Ascorbic acid:** No significant interference up to 16 mg/dL (0.9 mmol/L). Concentrations above the therapeutic levels will interfere and cause erroneous results. *Hyperlipemia or hyperproteinemia lead to a negative bias in the measurement of electrolyte because of dilution effect.*	 **Icterus :** No significant interference up to 60 mg/dL for conjugated and unconjugated bilirubin **Hemoglobin:** No significant interference up to an H index of 1000 (approximate haemoglobin concentration 1000 mg/dL). **Lipemia:** No significant interference up to an L index of 2000. There is a poor correlation between the L index (corresponds to turbidity) and triglycerides concentration

ISE CALIBRATORS	ELITech Clinical Systems Device (ISE Calibrator)	Predicate device (ROCHE Diagnostics CO2-L, Bicarbonate liquid with Roche Diagnostics Ammonia/Ethanol/CO2 Calibrator, K031879)
Traceability	According the following reference material : Na^+ : NIST SRM 919b K^+ : NIST SRM 918b Cl^- : NIST SRM 918b/919b Total CO_2 : NIST SRM 924a	This method has been standardized against primary standard traceable to NIST or NERL.
ISE Calibrators	***Composition:*** Aqueous solutions containing sodium, potassium, chloride and total CO_2 with 2 different levels of concentrations. Concentrations are lot-specific. The values are given in the vial labels. ***Storage:*** Store at 2-30 °C. These calibrators are stable until the expiry date stated on the label. Do not freeze. ***Stability:*** - Calibrators are stable until the expiry date stated on the label. - After opening, calibrators is stable 30 days when stored at 2-30 °C *Note: Calibrators should be immediately and tightly capped to prevent contamination and evaporation.*	**Calibrator kit** *Composition:* Aqueous buffer solution containing ammonia, ethanol and sodium bicarbonate with preservative. Liquid ready-to-use calibrators The concentrations of the calibrators components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers. *Storage* Store at 2-8°C. These calibrators are stable until the expiry date stated on the label. *Stability* : - After opening, calibrators is stable 8 weeks when stored at 2-8 °C provided that dispensing of the calibrator takes place without microbial contamination, e.g. by pouring out . *Note: Calibrators should be tightly when not in use.*

Conclusion

The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate devices in its intended use locations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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NOV 18 2011

Re: k111960
Trade Name: ELITech Clinical Systems ISE CO^2 Electrode,
ELITech Clinical Systems ISE CALIBRATORS
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Codes: KHS, JIX
Dated: November 14, 2011
Received: November 15, 2011

Dear Ms. Hutson

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111960

Device Name: _____ ELITech Clinical Systems ISE CO_2 Electrode

Indications for Use:

ISE CO2 electrode
The carbon dioxide electrode for the ELITech Clinical Systems Selectra ProM is intended for use for the quantitative in vitro diagnostic determination of Total CO2 in human serum and plasma. Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111960

Indications for Use Form

510(k) Number (if known): K111960

Device Name: _____ ELITech Clinical Systems ISE CALIBRATORS ____

Indications for Use:

ELITech Clinical Systems ISE Calibrators are used for the calibration of sodium (Na+), potassium (K+), chloride (Cl-) and carbon dioxide (Total CO_2) on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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